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RP-HPLC Method Development and Validation for Simultaneous Estimation of Tadalafil and Silodosin: A Comprehensive Review

Sulabh Parmar[1], Sahil Prajapati[2], Himanshu Suthar[3]
KALOL INSTITUTE OF PHARMACY, India

Abstract: ***Benign Prostatic Hyperplasia (BPH) is a prevalent condition in aging men, often managed with pharmacological interventions. The fixed-dose combination of Silodosin, an alpha-1 adrenergic receptor antagonist, and Tadalafil, a PDE5 inhibitor, has gained regulatory approval for BPH management. This review highlights the principles of RP-HPLC method development and validation for simultaneous estimation of these drugs in pharmaceutical dosage forms. It emphasizes chromatographic optimization, stability-indicating approaches, and adherence to ICH guidelines, ensuring accuracy, precision, and robustness.***

Keywords: Silodosin, Tadalafil, RP-HPLC, Analytical Method Development, Benign Prostatic Hyperplasia, Stability-Indicating Method

I. INTRODUCTION

Benign Prostatic Hyperplasia (BPH) is a non-cancerous enlargement of the prostate gland, leading to lower urinary tract symptoms. Combination therapy using Silodosin and Tadalafil addresses both urinary symptoms and erectile dysfunction. Analytical method development for such combinations is critical for quality control and regulatory compliance.

II. ANALYTICAL METHOD DEVELOPMENT

RP-HPLC is widely employed for simultaneous drug estimation due to its high resolution and reproducibility. Method development involves selecting appropriate chromatographic conditions, including mobile phase composition, column type, flow rate, and detection wavelength. Stability-indicating methods incorporate forced degradation studies under acidic, alkaline, oxidative, photolytic, and thermal conditions to ensure specificity.

III. DRUG PROFILES

Silodosin: A selective alpha-1A adrenergic receptor antagonist used for BPH management. It relaxes smooth muscles in the prostate and bladder neck, improving urine flow.

Tadalafil: A PDE5 inhibitor approved for erectile dysfunction and BPH. It enhances cGMP levels, promoting smooth muscle relaxation and improved urinary function.

IV. LITERATURE REVIEW

Several analytical methods have been reported for individual estimation of Silodosin and Tadalafil, including UV-spectrophotometry, HPLC, and LC-MS/MS. However, limited studies exist on simultaneous estimation using stability-indicating RP-HPLC methods, highlighting the need for robust analytical approaches.

V. REGULATORY PERSPECTIVE

The CDSCO approved the fixed-dose combination of Silodosin and Tadalafil for Phase III trials in 2024. ICH Q2(R1) guidelines mandate validation parameters such as specificity, linearity, accuracy, precision, LOD, LOQ, and robustness for analytical methods.

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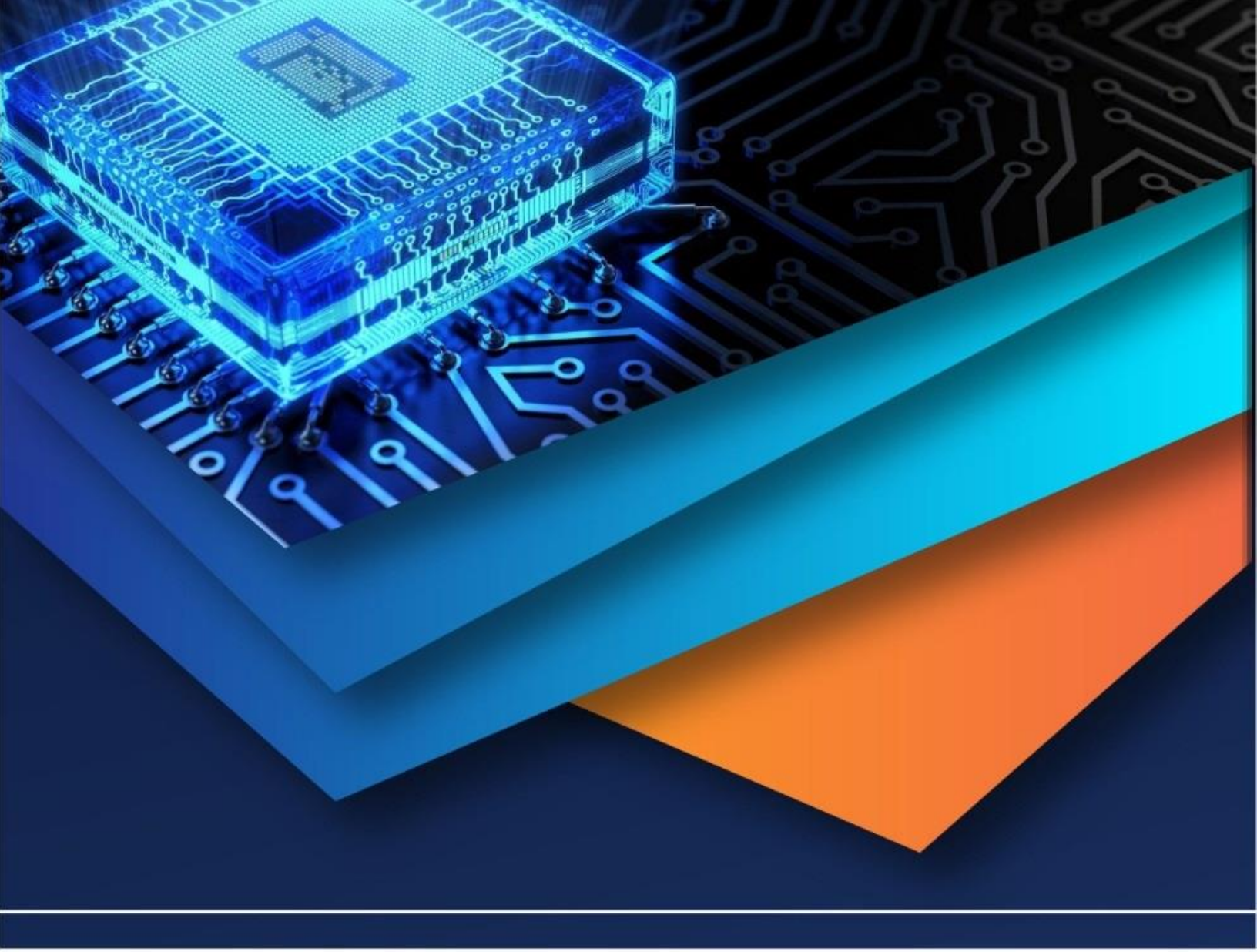
VI. FUTURE SCOPE & CONCLUSION

Developing a validated RP-HPLC method for simultaneous estimation of Silodosin and Tadalafil ensures reliable quality control and supports regulatory submissions. Future research may focus on applying Quality by Design (QbD) principles and exploring green analytical chemistry approaches for method optimization.

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